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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/671,329

09/25/2003

Hugh Herr

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21005

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HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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EXAMINER

EL-KAISSI, HIBA CARINE

ART UNIT

PAPER NUMBER

3762

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/671,329	HERR ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	HIBA EL-KAISSI	3762	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/25/2010 has been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-23 and 25-40 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, applicant discloses, "a device that modulates, by computer-controller actuation, a joint stiffness or damping of an ankle joint in an updating manner at least three times during each walk cycle for treating an ankle foot gait pathology".

a) "a device that modulates...a joint stiffness or damping of an ankle joint"

- this seems like a method step rather than an apparatus and "an ankle joint" is non-statutory subject matter and cannot be positively recited as part of an apparatus. Examiner suggests applicant use functional language such as

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“configured to”, “adapted to”, etc. EXAMPLE: “a device configured to modulate...”.

b) “in an updating manner at least three times” – is not disclosed in the specification, and it is vague and unclear what is meant by in an updating manner at least three times during each walk cycle. When and what are the three times? And what defines a walk cycle?

c) “during each walk cycle” --- is vague and unclear what is meant by “during each walk cycle” since no walking, or the number of walk cycles were previously claimed.

Regarding claim 2, applicant recites, “wherein the device includes an actuator that modulates the joint stiffness of a torsional spring control”.

a) “torsional spring control” is inferentially included and has not been positively recited. Examiner suggests applicant use functional language such as

“configured to”, “adapted to”, etc to positively recite “torsional spring control”.

EXAMPLE: “wherein the device includes an actuator configured to modulate...”,

Which places the torsional spring control for functional use recitation or, previous positively recite this control in the claim as it is unclear where the torsional spring control is coming from.

Regarding claim 3, please see the above rejection of claim 2, for the limitation of “spring-damper control”.

Regarding claim 4, applicant recites, “wherein the device includes....coupled to a foot portion of the orthosis”. “A foot portion” is inferentially included and has not been

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positively recited. Examiner suggests applicant previously recite wherein the orthosis comprises a foot portion, and/or use functional language to recite the coupling to the foot portion.

Regarding claim 10, applicant recites, “the orthosis is used to treat drop foot gait”. “Drop foot gait” constitutes of non-statutory subject matter and cannot be positively recited. Examiner suggests using functional language to functionally recite the use of the orthosis.

Regarding claim 11, applicant recites, “wherein the orthosis is used to treat a patient having....”. The patient and muscle weakness constitutes of non-statutory subject matter and cannot be positively recited. Examiner suggests using functional language to functionally recite the use of the orthosis.

Regarding claim 12, applicant recites, “attachable to a leg of a person.....attachable to a foot of a person”. The leg and foot of the person constitute of non-statutory subject matter and cannot be positively recited. Examiner suggests using functional language to functionally recite the use of the orthosis. Also in claim 12, applicant recites, “configured to act on a spring”. It is unclear where this spring is coming from, and how it is attached or part of the orthosis. Also in claim 12 applicant recites:

-- “in an updating manner at least three times” – is not disclosed in the specification, and it is vague and unclear what is meant by in an updating manner at least three times during each walk cycle. When and what are the three times? And what defines a walk cycle?

-- "during each walk cycle" --- is vague and unclear what is meant by "during each walk cycle" since no walking, or the number of walk cycles were previously claimed.

Regarding claim 13, this seems like a method step rather than an apparatus. Examiner suggests applicant use functional language, especially to positively recite "controller plantar flexion", "forefoot collisions" and "ground", as, "controller plantar flexion" and "forefoot collisions" are non-statutory subject matter and, ground is inferentially included.

Also in claim 13, applicant recites, "the spring deflection", which lacks antecedent basis.

Regarding claim 14, applicant recites, "wherein the actuator minimizes the joint stiffness or damping during late stance", seems like a method step rather than an apparatus. Examiner suggests applicant use functional language, especially to positively recite late stance, since late stance is non-statutory subject matter.

Regarding claim 15, please see rejection of claim 14.

Regarding claims 19 and 24, please see rejection above of claims 1 and 12 regarding "in an updating manner" and "three times during each walking cycle".

Regarding claim 25, applicant recites, "the actuator modulating a joint stiffness or damping of an ankle joint by controlling a spring compression in response to at least two sensed parameters during walking, the actuator modulating the joint stiffness or damping of the ankle joint by controlling the spring in at least two different modulation

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phases in an updating manner at least three times during each walking cycle in response to at least two sensed parameters”.

a) “modulating a joint stiffness or damping of an ankle joint” is vague and unclear, since this seems like a method step, and joint stiffness or damping of an ankle joint are non-statutory subject matter that cannot be claimed. Examiner suggests using functional language.

b) “by controlling a spring compression in response to at least two sensed parameters during walking”. It is unclear where the sensed parameters are coming from and how they are sensed. So, it is unclear how controlling a spring compression in response to a parameter that is unclear or unknown how it is sensed, with what element, and how that element is tied to the rest of the apparatus. Also spring compression is inferentially included, and should be positively recited using functional language. Also, “walking” is non-statutory subject matter.

c) “the actuator modulating the joint stiffness or damping of the ankle joint by controlling the spring in at least two different modulation phases”. The same applies as to parts a) and b) above, as to the limitation appearing to be a method step and lacking functional language for non-statutory subject matter. Also, “the spring in at least two different modulation phases”, “modulation phases” are inferentially included and not positively recited, and it is unclear what is meant by two different modulation phases. Walking phases? Ways of modulating? Modulation times?

d) “in an updating manner at least three times during each walking cycle in response to at least two sensed parameters”. Please see the rejections of claims 1 and

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12 above. Also, "in response to at least two sensed parameters". It is vague and unclear as to whether applicant is referring to the same sensed parameters previously recited, or two new different sensed parameters. Also, it is unclear how these parameters are sensed and how that element is tied to the rest of the apparatus.

Regarding claim 26, applicant recites, "the device further includes a spring linked to an actuator, wherein the actuator modulates the joint stiffness or damping of the ankle joint". It is unclear as to how the device "further includes", since in claim 1, it never included anything. Also, "an actuator" is inferentially included and has not been positively recited. Examiner suggests listing the actuator as a positive element as part of the orthosis or device, rather than including the actuator as a functional element as part of the "linking" from the spring. Also, "wherein the actuator modulates..." is vague and unclear since in claim 1, the whole device is modulating, however in claim 26, it is the actuator that is modulating. Since claim 26 discloses wherein the device includes a spring, it is assumed that the spring is part of the "modulation" step as well. Also, " joint stiffness or damping of the ankle joint" are non-statutory subject matter. Functional language needs to be recited in claims 1 and/or 26 in order to functionally recite these elements.

Regarding claim 27, this seems like a method step rather than an apparatus. Functional use recitation should be recited using functional language.

Regarding claim 28, see rejection of claim 27 above, also "a torsional spring-damper control" is inferentially included and has not been positively recited.



Regarding claim 29, applicant recites, "sensing one or parameters of the orthosis during walking". It is vague and unclear what is meant by "parameters of the orthosis" since it has not been disclosed in the specification, and it is unclear how the sensing is being done, since no element has been tied to the step of sensing.

Regarding claim 30, "the spring" lacks antecedent basis.

Regarding claim 31, please see rejections above of claims 1, 12, and 19. Also, "a spring associated with an orthosis". It is unclear what is meant by "associated". The relative term of degree is unclear.

Regarding claim 32, applicant recites, "receiving a parameter of a forefoot force signal during walking", which is vague and unclear since there is no element tied to the step and it is unclear how this is being done.

Regarding claim 34, applicant recites, "of a torsional spring control". It is unclear where this is coming from and how it is tied to the rest of the apparatus/method.

Regarding claim 35, see rejection above of claim 34, regarding "spring damper control".

Regarding claim 37, please see rejection above of claim 1. Also in claim 37, applicant recites, "adaptive in nature, whereby information from each gait cycle causes...". It is unclear what is meant by adaptive in nature, since it has not been disclosed in the specification. Also, "from each gait cycle" is vague and unclear since it is non-statutory subject matter that cannot be claimed, and it is unclear what "each" constitutes of since no gait cycles, or the number of cycles were previously claimed. Also, it is unclear what is meant by "information" since no information is being sensed in

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order to use it or further apply it or have it cause further modulation. Also, “joint impedance” is inferentially included and constitutes non-statutory subject matter, unless the joint impedance is being detected, and can then further be used. Also, one gait cycle to the next is inferentially included and constitutes non-statutory subject matter, and it is unclear where the gait is coming from since the functional act of walking, or movement, has not been previously recited.

Regarding claim 38, please see rejection above of claim 1. Also in claim 38, applicant recites, “adaptive in nature, whereby information from each gait cycle causes...”. It is unclear what is meant by adaptive in nature, since it has not been disclosed in the specification. Also, “from each gait cycle” is vague and unclear since it is non-statutory subject matter that cannot be claimed, and it is unclear what “each” constitutes of since no gait cycles, or the number of cycles were previously claimed. Also, it is unclear what is meant by “information” since no information is being sensed in order to use it or further apply it or have it cause further modulation. Also, “joint impedance” is inferentially included and constitutes non-statutory subject matter, unless the joint impedance is being detected, and can then further be used. Also, one gait cycle to the next is inferentially included and constitutes non-statutory subject matter, and it is unclear where the gait is coming from since the functional act of walking, or movement, has not been previously recited.

. Regarding claim 39, please see rejection above of claim 1. Also in claim 39, applicant recites, “adaptive in nature, whereby information from each gait cycle causes...”. It is unclear what is meant by adaptive in nature, since it has not been

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disclosed in the specification. Also, "from each gait cycle" is vague and unclear since it is non-statutory subject matter that cannot be claimed, and it is unclear what "each" constitutes of since no gait cycles, or the number of cycles were previously claimed. Also, it is unclear what is meant by "information" since no information is being sensed in order to use it or further apply it or have it cause further modulation. Also, "joint impedance" is inferentially included and constitutes non-statutory subject matter, unless the joint impedance is being detected, and can then further be used. Also, one gait cycle to the next is inferentially included and constitutes non-statutory subject matter, and it is unclear where the gait is coming from since the functional act of walking, or movement, has not been previously recited.

Regarding claim 40, please see the rejections of the independent claims above.

Regarding claim 41, please see the rejections of the independent claims above.

***Claim Rejections - 35 USC § 102***

***Claim Rejections - 35 USC § 103***

Please see previous Final Office Action dated 11/06/2009 for the rejections of the claims.

In light of the 112 2<sup>nd</sup> rejections, Examiner further suggests positively reciting and claiming an impedance limitation, such as actively adjusting, varying, or selectively varying, joint impedance, if that is what applicant believes is the novel aspect of the

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independent claims; because as is the claim does not positively recite modulating any impedance or detecting any impedance in order to change the impedance as part of the orthosis.

Examiner also notes of the following pertinent prior arts not of record:

1) Deffenbaugh et al.; US 2001/0029400, abstract, Fig. 1, Fig. 4, 0017, 0073-0075, 0080, 0082, 0084, 0094-0096, 0203, 0222, at the least.

2) Herr et al., 2002/0052663 -- wherein the claims are obvious over the prior art, such that even though the prior art is suggested for a knee prosthesis, the same can be applied to the ankle, to one of ordinary skill in the art.

3) Koniuk; US 6443993 – abstract, Fig. 3 and the supporting paragraphs.

4) Martin; US 2004/0054423 --- abstract, paragraphs 0005, 0015, 0029, Fig. 13, Fig. 14, 0113, 0115, 0116, 0131, 0132, 0149, 0156, 0162, 0166-0172, 0175, at the last.

5) Yasui; US 7641700

6) Dariush; US 7650204

7) Bedard et al; US 7736394

8) Bedard et al.; US 7867284

### ***Response to Arguments***

Regarding applicant's arguments filed on 03/25/2010 have been fully considered, however are not persuasive.

Regarding the prior art of record, Beard and other references regarding impedance, applicant argues that the references simply do not disclose impedance or a variable-impedance orthosis. In light of the above 112 rejections, Examiner notes that the impedance was never positively recited, and would be read as a functional use recitation, rather than a positive limitation. It is true that the preamble should be considered as part of the claim, but as breathing life into the claim.

Therefore, Examiner suggests applicant maybe positively recite an impedance limitation, such as actively adjusting, varying, or selectively varying, joint impedance, if that is what applicant believes is the differences with Beard, and an important aspect of the independent claims; because as is the claim does not positively recite modulating any impedance or detecting any impedance in order to change the impedance.

Also, the references disclosing walking cycles, Examiner notes that a third walking cycle, versus two walking cycles, would be obvious to one of ordinary skill in the art, and is not of innovation.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HIBA EL-KAISSI whose telephone number is (571)270-5617. The examiner can normally be reached on Monday- Friday 9 a.m - 6 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571)272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/HIBA EL-KAISSI/

Examiner, Art Unit 3762

/Niketa I. Patel/

Supervisory Patent Examiner, Art Unit 3762